

## Advancing Innovation and Convergence In Cancer Research

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**Health Sciences Director** 

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Office of the Director, National Cancer Institute (NCI)
National Institutes of Health (NIH)



2015 ASEE Engineering Research Council Annual Meeting
Change and Research Opportunities: Perspectives from NIST, DOE, NGA, and NCI

March 10, 2015



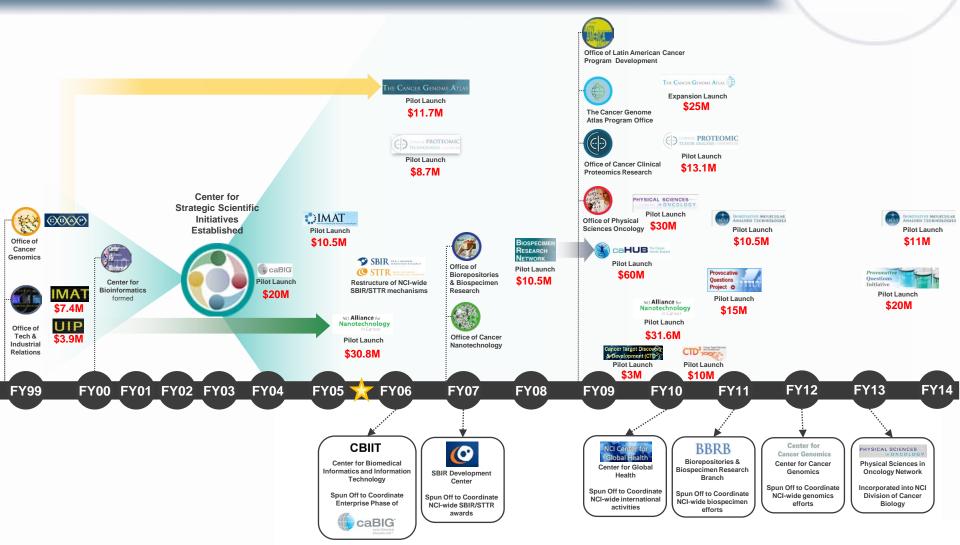






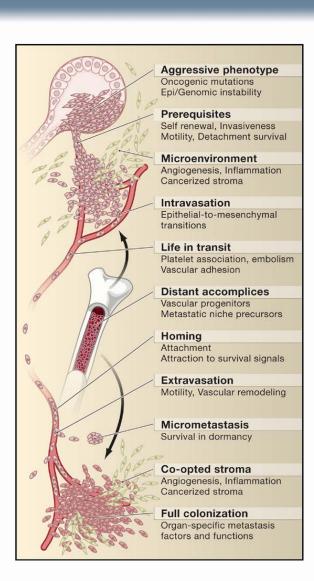
## NCI Center for Strategic Scientific Initiatives (FY99 – FY14)





## What is It? Tumor, Cancer, and Metastasis





#### 5 year Relative Survival Rates

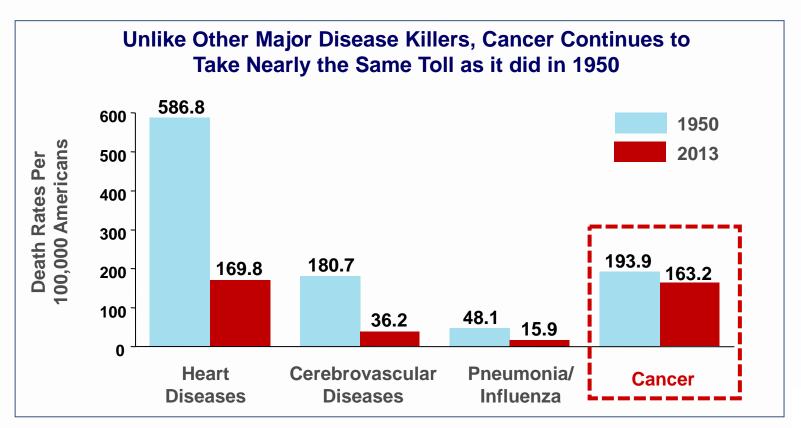
Organ Site	All Stages	Localized	Regional	Distant
Prostate	99	>99	>99	28
Breast	89	99	85	25
Ovary	45	92	72	27
Uterine Cervix	68	91	57	16
Melanoma	91	98	63	16
Urinary Bladder	77	69	34	6
Kidney	72	92	65	12
Colon and rectum	65	90	71	13
Esophagus	18	40	21	4
Lung and bronchus	17	54	27	4
Liver	17	30	11	3
Pancreas	7	26	10	2

"...>90% of deaths are caused by disseminated disease or metastasis...

## In the U.S., Cancer Continues to Represent an Enormous Burden

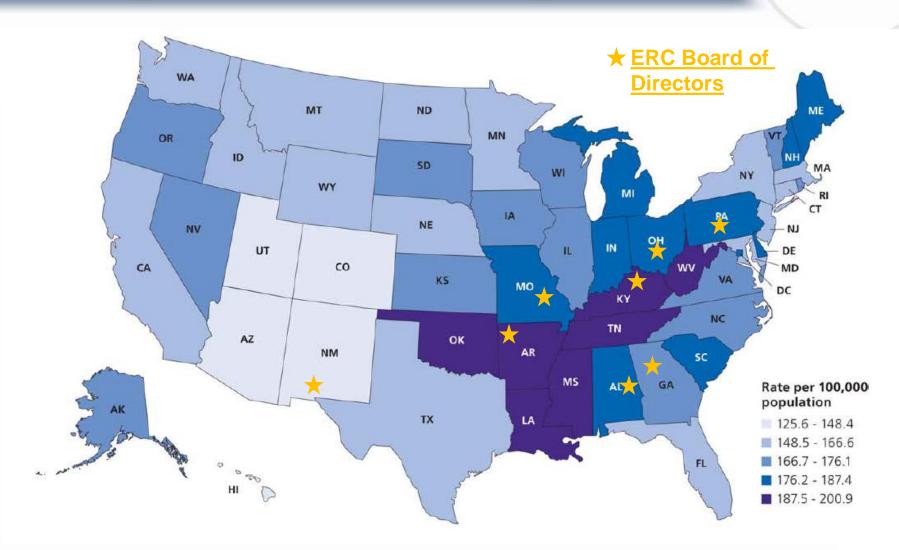


- 576,691 Americans died of cancer in 2011 (589,430 projected for 2015)
- 1,658,370 Americans will be newly diagnosed with cancer in 2015 (projected)
- \$157 billion in 2010 for cancer healthcare costs (\$173 billion projected in 2020)



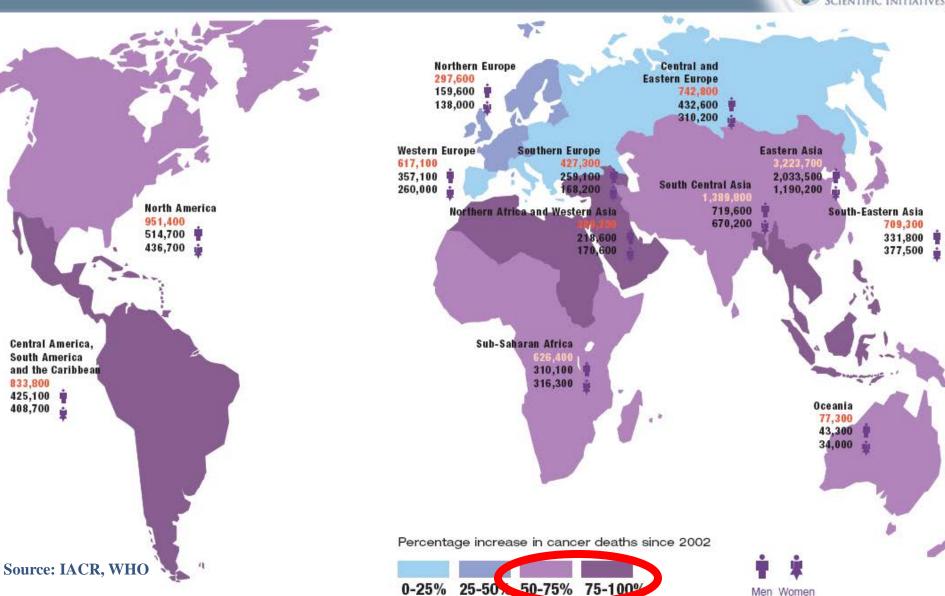
## US Geographic Patterns in Cancer Death Rates in 2011





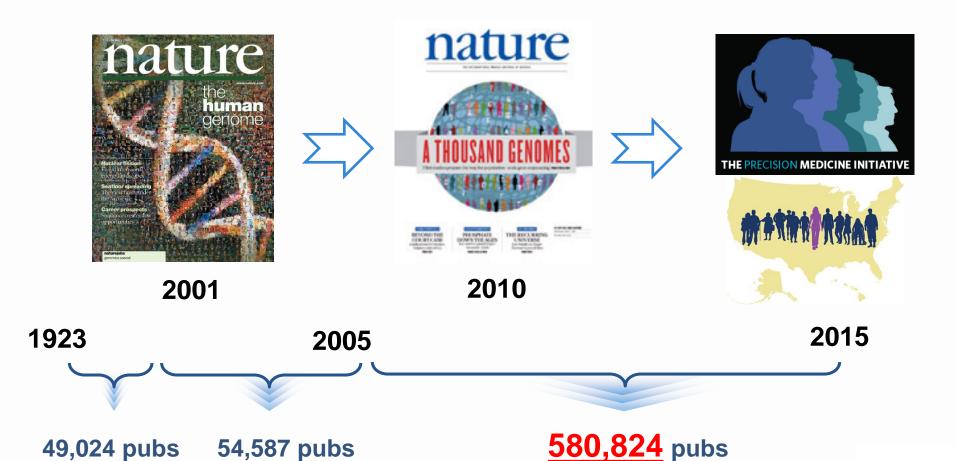
## Global Burden: By 2020, Cancer Incidence 16 M/yr (Mortality 10 M/yr)





# Unprecedented Amount of Scientific Knowledge: Omics(ssss)

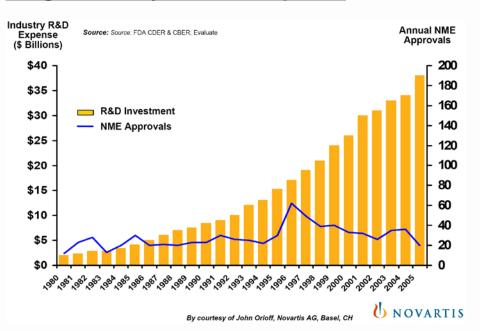




## Is More Knowledge Yielding More Solutions for Patients?

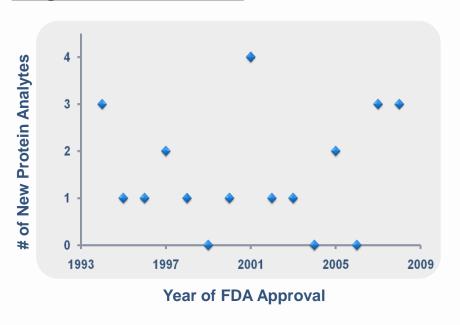


#### **Drug Discovery and Development**



- 10 15 years at ~ \$1.8 billion\*
- 2007: 19 NMEs [lowest since 1983]
- 2008: 21 NMEs [29% new-in-class]
- 2009: 24 NMEs [17% new-in-class]

### **Diagnostic Biomarkers**

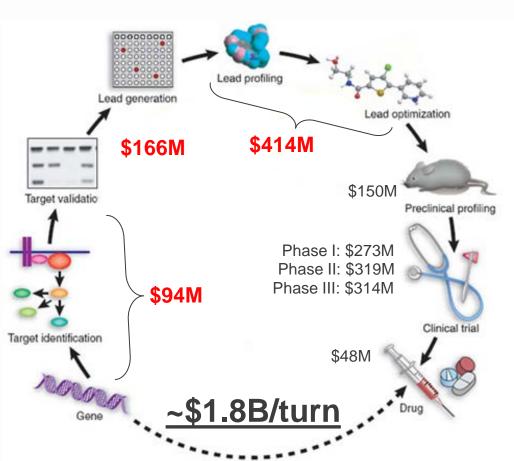


- Averaging 1.5 FDA approvals per year<sup>†</sup>
- 1000's of samples
- Balancing complexity of biology against heterogeneity of patients

### Maybe...but can it be more efficient?

## Translation Pace: How To Break Out of Current Paradigm?





### Turning the Crank...

### **Key Needs (from community '02)**

- Standards and protocols
- Real-time, public release of data
- Large, multi-disciplinary teams
- Pilot-friendly team environment to share failures and successes
- Team members with trans-disciplinary training

The potential to transform cancer drug discovery and diagnostics



### National Institutes of Health (NIH): 27 Institutes and Centers









































**NIDDK** 



**FIC** 

































### NIH Budget ~ \$30.14 Billion (FY14)

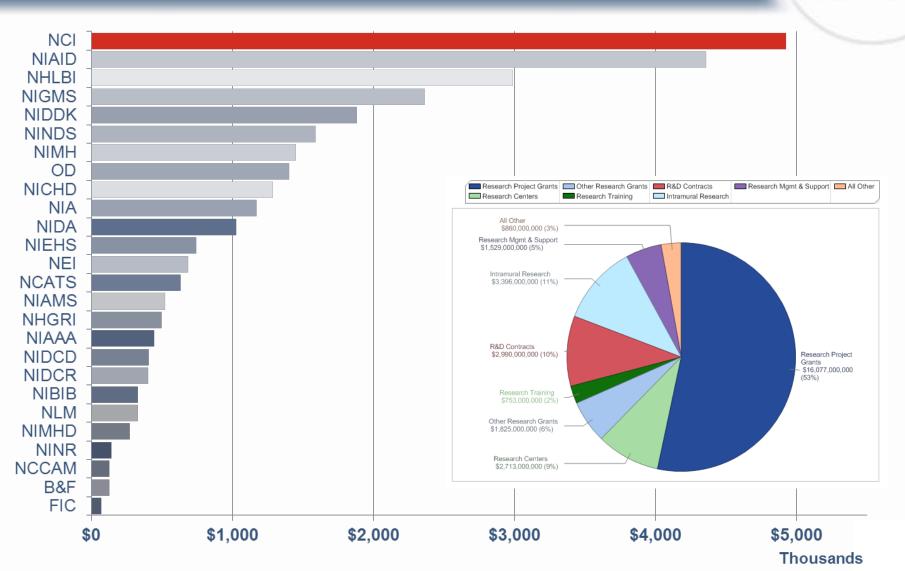
- ~81% for extramural support
- ~60,000 grants and contracts

### NCI Budget ~ \$4.92 Billion (FY14)

- ~ 75% for extramural support
- ~7,500 grants and contracts

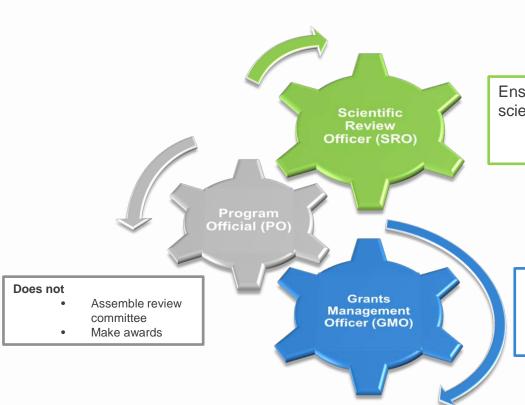
## National Institutes of Health (NIH): 27 Institutes and Centers [FY14]





## The NIH Extramural Team: Checks & Balances





Ensure **fair** and **unbiased** evaluation of the scientific and technical merit of proposed research

- Manages study sections
- Prepares/issues summary statements

Ensure all required business management actions are performed by the grantee and federal government

- Participates in budget negotiations
- Prepares/issues Notice of Awards (NoA)

## NIH: Types of Funding Announcements (FOAs)



http://grants.nih.gov/grants/planning\_application.htm

Types of Funding Opportunity
Announcements (FOA)

~685 in FY14







#### **Parent Announcements**

- Non-specific, investigator-initiated "unsolicited" research
- May submit any topic within the breadth of the NIH mission.
- No money set-aside
- Competition tied mainly to an IC's overall payline

### IC-Specific Program Announcements (PA)

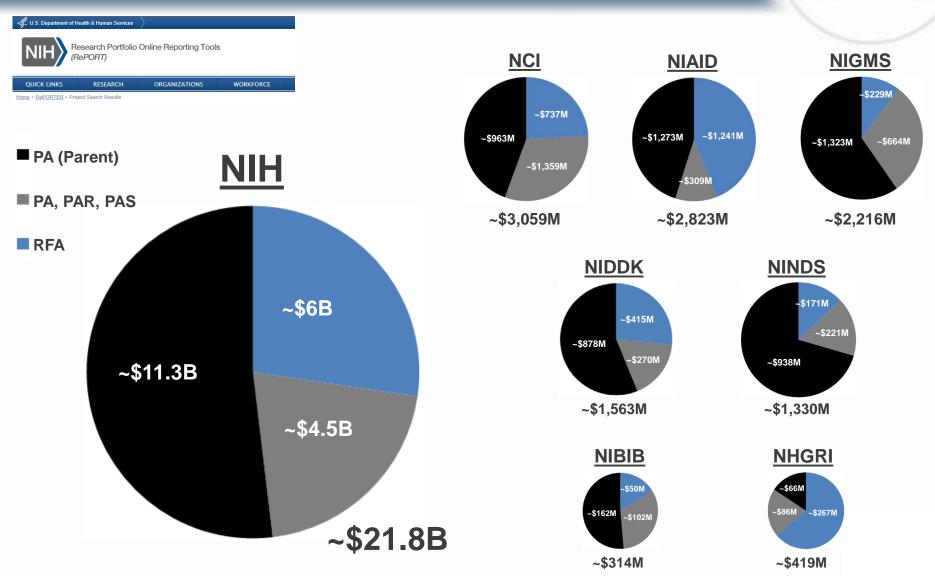
- Often broadly defined or a reminder of a scientific need
- Investigator-initiated
   "unsolicited" research
- No money set asides (unless PAS)
- Competition tied mainly to the IC's overall payline
- High-priority applications may be funded beyond the payline

### Requests for Applications (RFA)

- NIH-Requested Research; Well-defined scientific area
- Specifies funds and targets number of awards
- Competition depends on number of applicants and dollars set aside

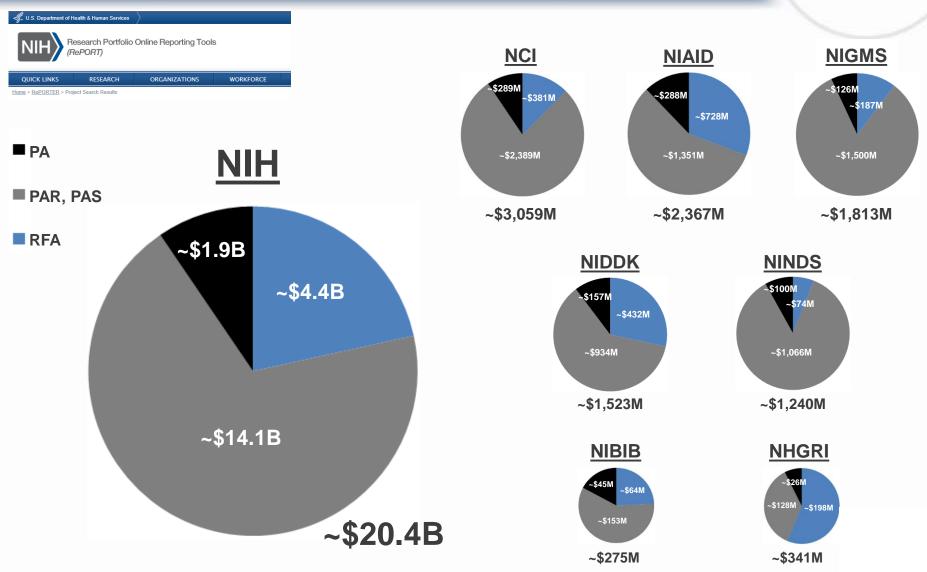
## NIH Research Portfolio Online Reporting Tools (RePORT) [FY14]





## NIH Research Portfolio Online Reporting Tools (RePORT) [FY04]





## National Cancer Program: Stakeholders



~\$18 B per year



Private Industry \$9.2 B NCI \$5 B

Fed/State \$3.4 B





NPO/Foundations, \$0.6 B

## **National Cancer Institute** Organization





Director Harold Varmus, MD

### **National Cancer** Institute

\$4.79B (FY13)

**Deputy Director** Office of the

**CSSI** 

**Director** 

~\$110 M (~3%)

Center for Cancer Research

**Division of** Cancer **Epidemiology** and Genetics

~\$812M (~17%)

**Division of** Cancer Treatment and **Diagnosis** 

~\$1,166M (~32%)

**Division of** Cancer **Biology** 

~\$726M (~20%)

**Division of** Cancer **Control** and **Population Sciences** 

~\$398M (~11%)

**Division of** Cancer **Prevention** 

Douglas Lowy, MD

~\$249M (~7%)

**Division of Extramural Activities** 

~\$22M (~0.5%)

**Conducting – Intramural** 

**Funding – Extramural** 

# NCI 2013 Fact Book: FY13 Budget Breakdown

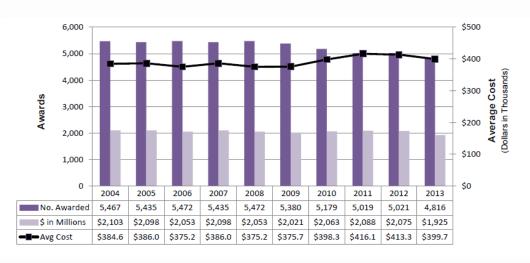


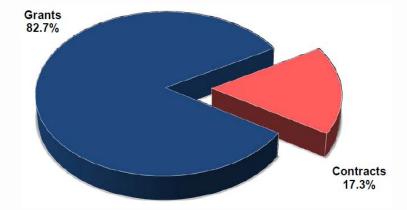


#### Fiscal Year 2013 Budget

(Dollars in Thousands)

Mechanism	Amount	Percent
Contracts:		
Research & Development (R&D) Contracts	\$616,046	17.1%
Buildings and Facilities	7,904	0.2%
Construction Contracts	0	0.0%
Subtotal Contracts	623,950	17.3%
Grants:		
Research Project Grants (RPGs)	2,000,161	55.4%
Cancer Centers/Specialized Centers/SPORES	533,951	14.8%
NRSA	65,788	1.8%
Other Research Grants	387,538	10.7%
Construction Grants	0	0.0%
Subtotal Grants	2,987,438	82.7%
Total Extramural Funds	3,611,388	100.0%
Total Intramural/RMS	1,177,626	
*Total NCI	\$4,789,014	





## NCI's Federally Funded Research and Development Center (FFRDC)



operated by Leidos Biomedical Research, Inc.

Frederick National Laboratory for Cancer Research Established in 1972 as one of the nation's 39 FFRDC's and the only one devoted exclusively to biomedical research and development

#### **Facts**

As one of Frederick County's major employers, the contractor Leidos Biomedical Research Inc. employs approximately 1,800 employees.

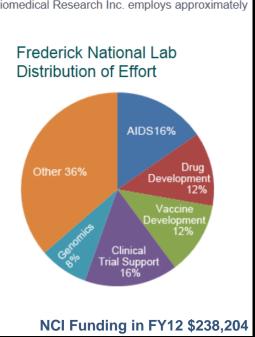
#### **Economic Impact**

In addition to payroll, Leidos Biomedical Research contributes:

- Dollars spent via Leidos Biomedical Research (formerly SAIC-Frederick) purchase orders, Contract Year 2011
  - Frederick County...\$16,820,351
  - Maryland.....\$183,086,783
- Dollars spent via Leidos Biomedical Research (formerly SAIC-Frederick) purchase orders, 9/26/08–8/10/11
  - Frederick County...\$35.695.585
  - Maryland.....\$286.944.880

#### Physical

- 68 acres deeded to the Department of Health and Human Services (HHS)
- · 991.217 net square feet
- 1,654,035 gross square feet
- 113 buildings on site

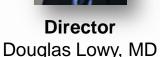




## NCI Center for Strategic Scientific Initiatives (CSSI): Concept Shop











**Deputy Director** Jerry S.H. Lee, PhD

#### **Mission**

"...to create and uniquely implement exploratory programs focused on the development and integration of advanced technologies, <u>trans-disciplinary approaches, infrastructures, and standards</u>, to accelerate the <u>creation and broad deployment</u> of <u>data, knowledge, and tools</u> to empower the <u>entire cancer research continuum</u> in better understanding and leveraging knowledge of the cancer biology space <u>for patient benefit</u>..."









2003, 2007, 2011, 2013, 2014

2005, 2010

2008, 2013\*

2011, 2014







2004, 2008, 2014

2005, 2008

2010

## Support Convergence and Innovation At Many Scales





Phase II



Early settlers



PHYSICAL SCIENCES in ONCOLOGY



Phase II



Phase II



Team Explorers







Discoverers/ Pioneers

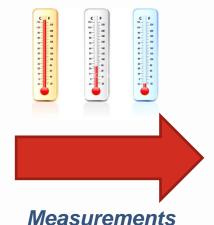
Basic Applied Translational Clinical Commercial/Industry

## Center Framework: "What is Water?"- Measurements → Insights





Color (clear, yellow, brown)
Taste (none, metallic, awful)



Taken

LOTS of Quantitative "Data"

But also LOTS of





Phase (liquid, gas, solid)
Phase change (boil, melt, freeze)





**Qualitative Descriptions** 

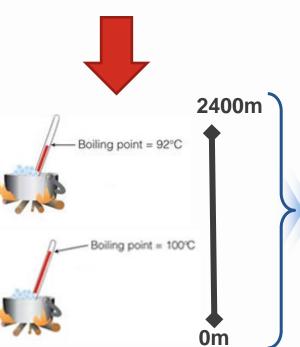
# Standards and Sharing of Data → New Insights and Understanding

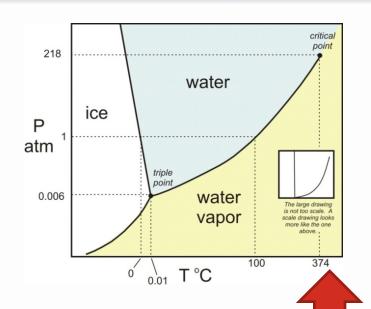


- Define samples & protocols
- Share collected data





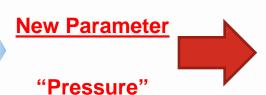




### New Understanding

- Phase boundaries
  - V/L equilibrium
- Triple Point

(Phase Diagram)



Saturated steam			Superheated steam			
Pressure (kg/cm <sup>2)</sup>	Temp (°C)	Vapour enthalpy (keal/kg)	Specific volume (m <sup>2</sup> /kg)	Density (kg/mi)	Specific v (m/l at 250°C	
1	99.1	638.8	1.725	0.580	2.454	2.691
2	119.6	646.2	0.902	1,109	1.223	1.342
3	132.9	650.6	0,617	1,621	0.812	0.893
4	142.9	653.7	0.471	2,123	0,607	0.668
5	151.1	656.0	0.382	2,618	0,484	0.533
6	158.1	657.0	0.321	3.115	0.402	0.443
7	164,2	659.5	0.278	3,597	0.343	0.379
8	169,6	660.8	0.245	4.082	0.299	0.331
9	174,5	661.9	0.219	4,566	0.265	0.293
10	179.1	662.9	0.198	5,051	0.238	0.263
12	187,1	664,5	0,166	6,024	0,196	0,218
14	194,1	665,7	0,143	6,993	0,167	0,186
16	200,4	666,7	0,126	7,937	0,145	0,162
18	206,1	667,4	0,112	8,929	0,128	0,143
20	211,4	668,0	0,101	9,901	0,114	0,128
22	216,2	668,4	0,092	10,870	0,103	0,116
24	220,7	668,7	0,085	11,765	0,093	0,106
26	225,0	669,0	0,078	12,821	0,085	0,097
28	229,0	669,1	0,073	13,699	0,078	0,089
30	232,7	669,2	0,068	14,706	0,072	0,083

LOTS of
Quantitative
and
Reproducible
Data

(Steam Table)

### 2003 Launch of the Technology Dashboard of CSSI: IMAT





### INNOVATIVE MOLECULAR

To support the **development**, **maturation**, and dissemination ANALYSIS TECHNOLOGIES of innovative and/or potentially transformative next-generation technologies

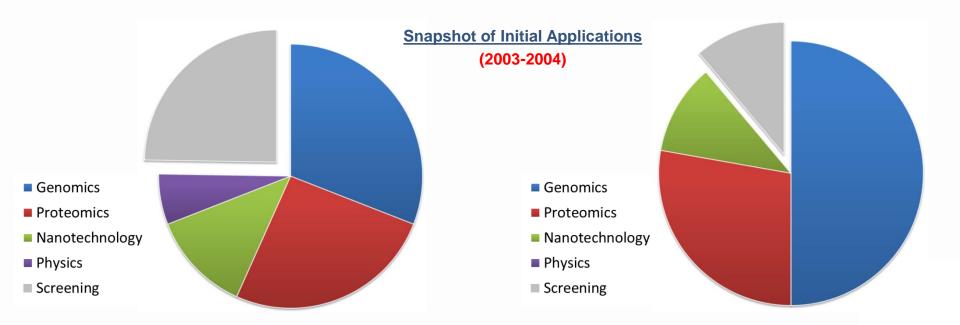
### **Innovative Technologies for Molecular Analysis** of Cancer

- Proof-of-concept technologies/projects encouraged
- Milestone and technology development driven (no biology)



### **Application of Emerging Technologies** for Cancer Research

- Validation and dissemination of platforms
- Demonstration of impact on basic and clinical research



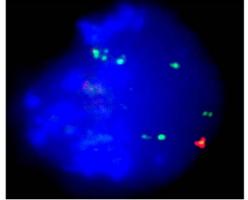
## First Step(back)- Cancer Genomics: Taking a Page from Engineers

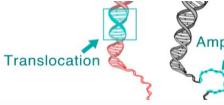


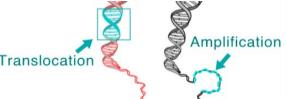
#### **Disease of Genomic Alterations**

- Copy number
- **Expression** (regulation of)
- **Regulation of translation**
- **Mutations**
- **Epigenome**









- Systematic identification of all genomic changes
- Repeat (<500) for individual cancer</li>
- Replicate for as many cancers as possible
- Make it publically available

Saturated steam			St	iperheated s	team	
Pressure (kg/cm²)	Temp (°C)	Vapour enthalpy	Specific volume (m <sup>2</sup> /kg)	Density (kg/m <sub>i</sub> )	Specific v (moli at 250°C	
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5	151,1	656,0	0,382	2,618	0,484	0,533
6	158,1	657,0	0,321	3,115	0,402	0,443
7	164,2	659,5	0,278	3,597	0,343	0,379
8	169,6	660,8	0,245	4,082	0,299	0,331
9	174,5	661,9	0,219	4,566	0,265	0,293
10	179,1	662,9	0,198	5,051	0,238	0,263
12	187,1	664,5	0,166	6,024	0,196	0,218
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22	216,2	668,4	0.092	10.870	0.103	0.116
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26	225.0	669.0	0.078	12.821	0.085	0.097
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30	232,7	669,2	0,068	14,706	0,072	0,083

**Steam table (Reference)** 

# Many "Thermometers": Heterogeneity of Platforms





454



Illumina



SOLiD



**Complete Genomics** 



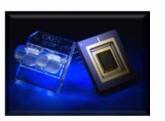
**Helicos** 



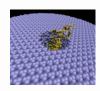
Visigen



**PacBio** 



**Ion-Torrent** 



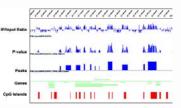
**Oxford Molecular** 



**NABsys** 



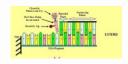
Nimblegen



febit Febit

LaserGen, Inc.

LaserGen



**Intelligent Biosystems** 



**ZSGenetics** 



Halycon

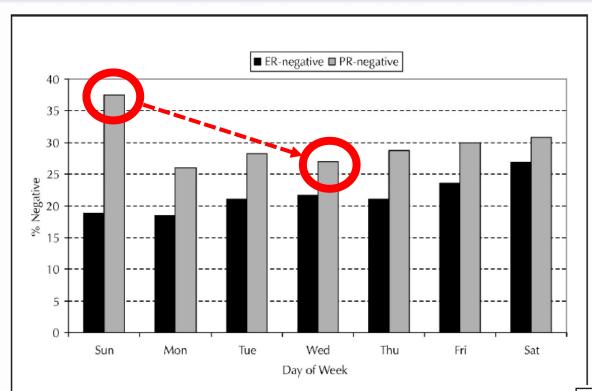




**Agilent** 

## **Unanticipated Innovation: Samples <u>AND</u> Handling Matter!**







"Garbage In...Garbage Out"

"...We found that specimens obtained late in the week (prolonged specimen handling) are more likely to be ER/PR negative than specimens obtained on other weekdays (regular specimen handling)..."

Table 1. Frequency of Specimen Removal by Day the Week	of
--	----

the Week					
Cases	ER-Negative	PR-Negative			
16	3	6			
1252	230	325			
1176	248	332			
784	170	212			
904	191	259			
919	216	276			
26	7	8			
5077	1065	1418			
	Cases  16 1252 1176 784 904 919 26	16 3 1252 230 1176 248 784 170 904 191 919 216 26 7			

Nkoy et. al., Arch Pathol Lab Med, April 2010

Abbreviations

### TCGA: Connecting Multiple Standardized Sources, Experiments, and Data Types

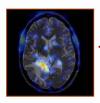




#### **Three Cancers- Pilot**

### Multiple data types

glioblastoma multiforme (brain)



Resource with more than 13 Tissue Source Sites

**Biospecimen Core** 

**Pathologic status** Tissue anatomic site **Surgical history** 

**Clinical diagnosis** 

**Treatment history** 

Histologic diagnosis

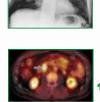
**Gene expression Chromosomal copy** number

Loss of heterozygosity

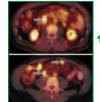
**Methylation patterns** 

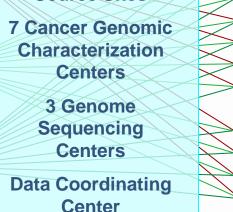
miRNA expression **DNA** sequence

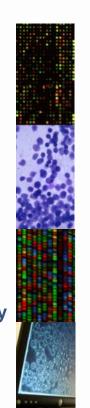
squamous carcinoma (lung)



serous cystadenocarcinoma (ovarian)







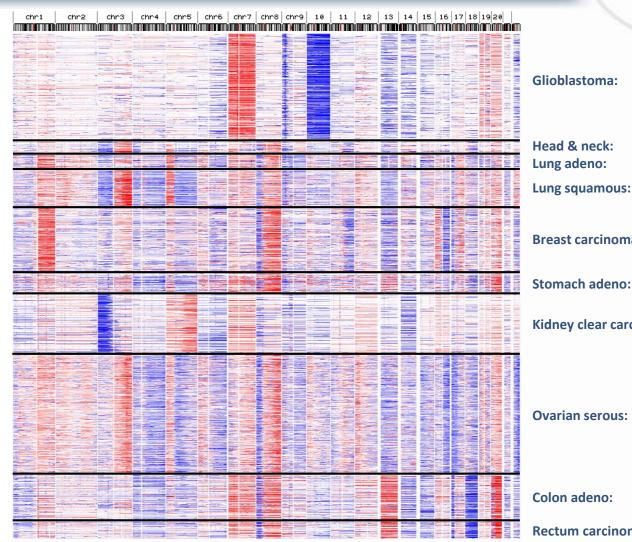
## **Genomic** "Steam Table"





#### <u>Summer 2011</u>





Glioblastoma:	470

ead & neck:	51
ing adeno:	57
ing squamous:	159

reast carcinoma:	180
------------------	-----

omach	adeno:	84	1
omach	adeno:	84	1

Ovarian serous: 520

Colon adeno: 198

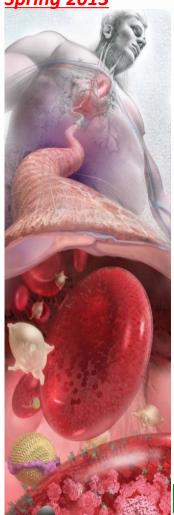
Rectum carcinoma: 74

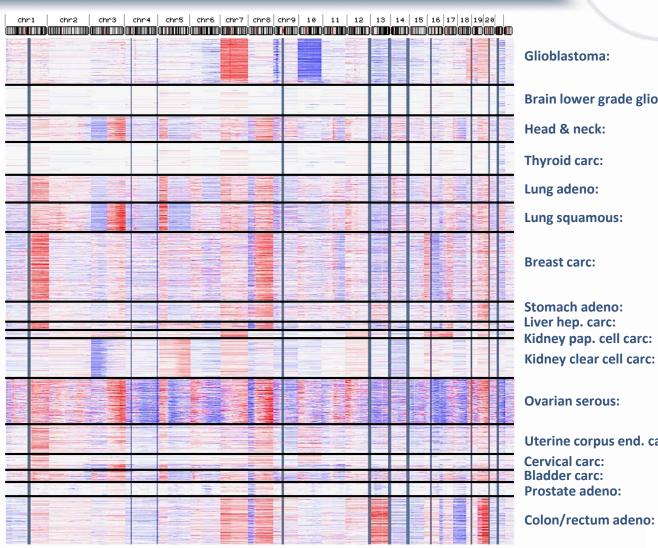
## Genomic "Steam Table"





**Spring 2013** 





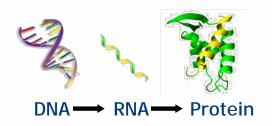
Glioblastoma:	56
Brain lower grade glioma:	180
Head & neck:	30
Thyroid carc:	401
Lung adeno:	35
Lung squamous:	343
Breast carc:	86
Stomach adeno: Liver hep. carc: Kidney pap. cell carc:	23 <sup>1</sup> 9 <sup>1</sup> 10 <sup>3</sup>
Kidney clear cell carc:	493
Ovarian serous:	559
Uterine corpus end. carc:	49
Cervical carc: Bladder carc: Prostate adeno:	102 135 171

575

## Clinical Proteomic Tumor Analysis Centers (CPTAC Phase II)



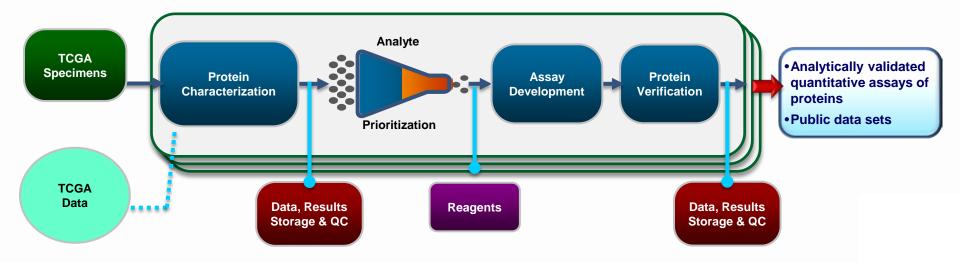
#### **Phase II Launched Sept 2011**



- Analyze matched TCGA samples using two approaches
  - Targeting genome to proteome
  - Mapping proteome to genome
- Develop validated and quantitative assays and reagents
  - Lessons from Phase I (mock 510K submission)
  - Antibody Characterization Lab



Distribute raw and analyzed data via public data portal

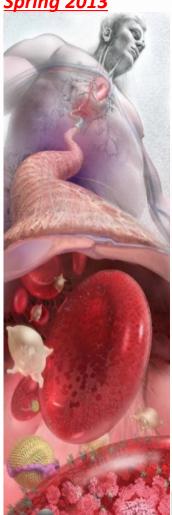


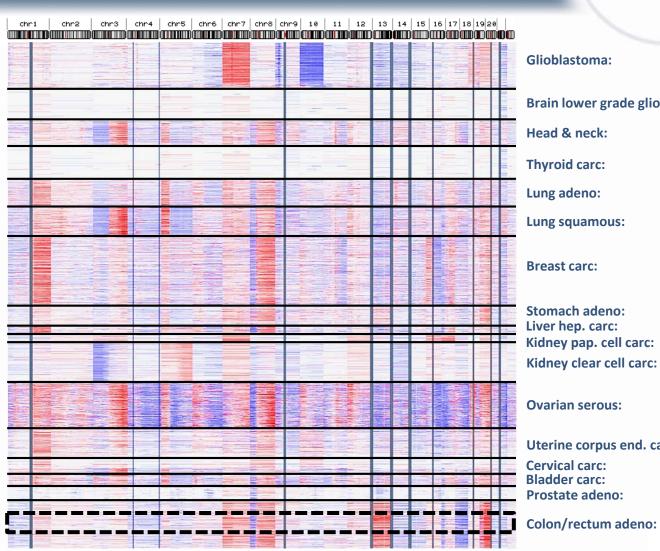
### Genomic "Steam Table"





**Spring 2013** 





Glioblastoma:	563
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Lung adeno:	356
Lung squamous:	343
Breast carc:	866
Stomach adeno: Liver hep. carc: Kidney pap. cell carc:	237 97 103
Kidney clear cell carc:	493
Ovarian serous:	559
Uterine corpus end. carc:	492
Cervical carc: Bladder carc: Prostate adeno:	102 135 171

575

## Colorectal Cancer: Global proteome reveals 2 new subtypes



## Transcriptome Subtypes

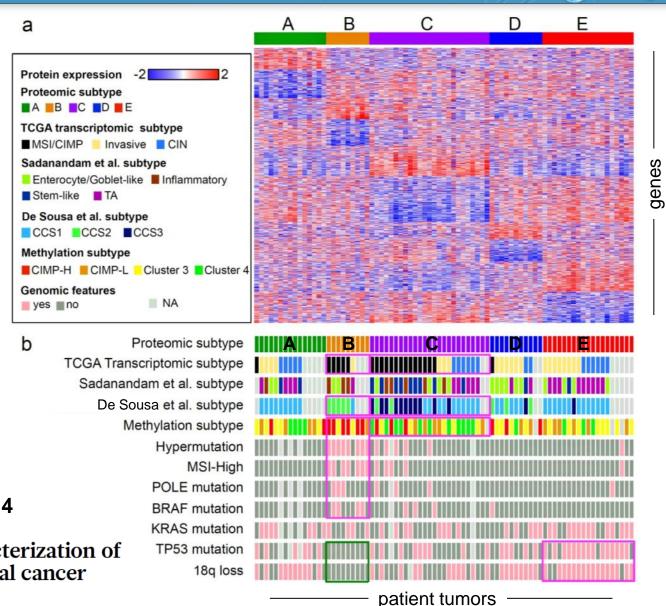
- MSI/CIMP
- Invasive
- CIN

### Proteome Subtypes

- A
- B
- C
- D
- E

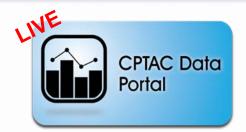


Proteogenomic characterization of human colon and rectal cancer

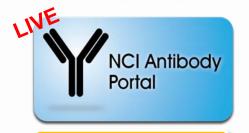


## CPTAC Public Resources: http://proteomics.cancer.gov





32,273 files (6.5 TB)



314 mAbs (~\$35)



554 assays



# of Samples

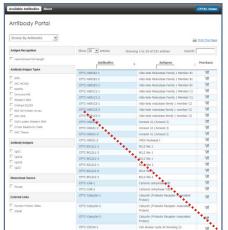
95

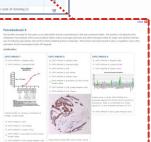
105

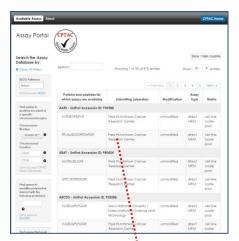
~8,000 proteins

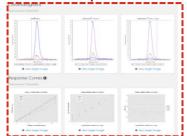
174\*\* ~10,000 proteins

~12,000 phospho-proteins









\*\*32 samples with global, phospho, and glyco-proteomics data

Disease

Colorectal

**Breast** 

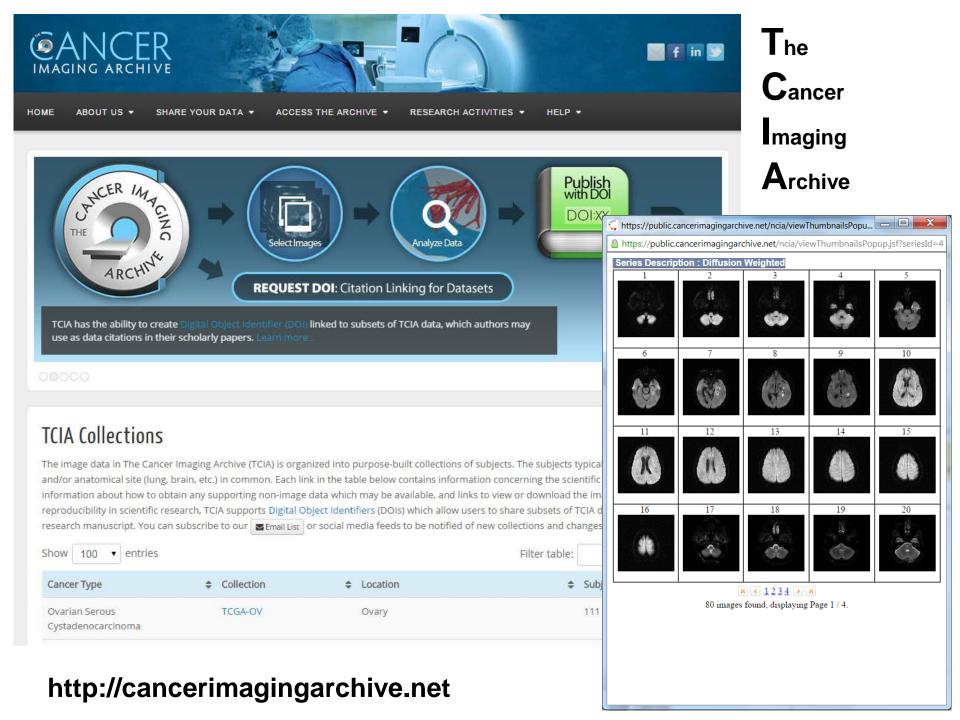
**Ovarian** 

Release Date

9/4/2013

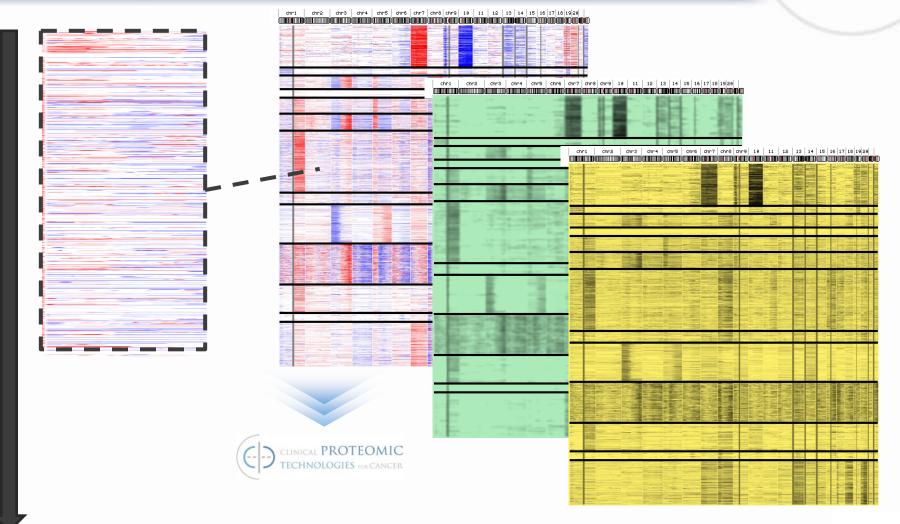
2/20/2014

6/16/2014

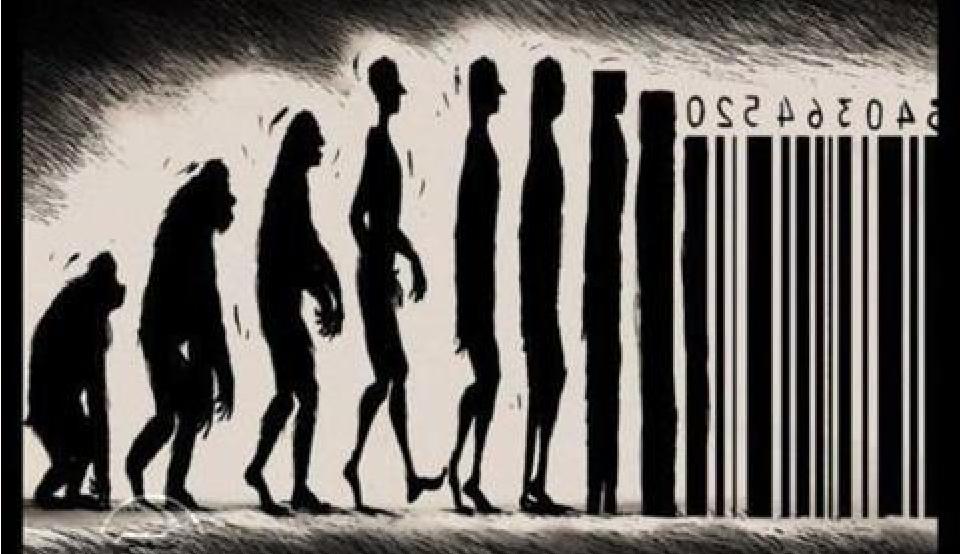


# Where Do We Go From Here? Is it <u>JUST</u> More Data?





Time? (Evolution)





## Physical Sciences-Oncology Network (PS-ON): Phase II

PHYSICAL SCIENCES inONCOLOGY

**FY09** 

**FY14** 



**FY19** 

Pre-Award > RFA-CA09-009

**PS-ON PARS** 

Thematic Areas: The Physical Dynamics of Cancer | Spatial Organization and Cancer

### **PS-OC PAR - PAR-14-169**

- U54 mechanism up to \$1.5M (DC)/year
  - 2-3 Projects/Center
  - Education/Outreach Unit
  - Pilot/Trans-Network Projects
- Competition under Type 1 (i.e., new Centers)
- 3<sup>rd</sup> Receipt Date Nov 26, 2015 (LOI Oct 14, 2015)

### **PS-OP PAR - PAR-15-021**

- U01 mechanism up to \$500K (DC)/year
  - 1 Project
  - **Trans-Network Projects**
  - Pilot Projects Optional
- 2<sup>nd</sup> Receipt Date Nov 26, 2015 (LOI Oct 14, 2015)







## NCI Alliance for Nanotechnology in Cancer (Phase III)



### **Cancer Research**

АR

Future Opportunities in Cancer Nanotechnology - NCI Stra Meeting Report

Piotr Grodzinski and Dorothy Farrell

Cancer Res Published OnlineFirst January 10, 2014.

NCI **Alliance** for **Nanotechnology** in Cancer



Piotr Grodzinski, PhD piotr.grodzinski@nih.gov

### PAR-14-285: Innovative Research in Cancer Nanotechnology (IRCN)

- U01 Mechanism up to \$450K in Direct Cost per year [5 years total]
- Milestone-driven focus on developing further understanding of nanomaterial interactions with biological systems and the mechanisms of nanoparticle delivery to the <u>desirable</u> and <u>intended cancer targets</u> in vivo
- 2nd Receipt Date April 15, 2015; Total of 6 receipt dates

### NOT-CA-14-035: Nanotechnology Research Training Program

- T32 Mechanism
- Support for the development and operation of cancer nanotechnology research training programs to educate graduate students and postdoctoral fellows in the multi-disciplinary field of cancer nanotechnology research
- Next Receipt Date May 25, 2015; Standard receipt dates

## Provocative Question (PQ) Initiative: Renewed for FY15 [\$20M]







NATURE | COMMENT

Science funding: Provocative questions in cancer

Nature Jan 26, 2012

#### **Program Objective:**

Challenge the scientific community to creatively think about and answer <u>important</u>, <u>but non-obvious or understudied</u>, provocative questions (PQs) in cancer research

Phase 1: PQs solicited through website and workshops [~\$21M/yr]

- FY12
  - 24 original PQs for R01/R21 apps (56 awards)
- FY13
  - 24 new PQs for R01/R21 apps (29 awards)
- FY14
  - 24 final PQs for R01/R21 apps (83 awards)

Phase 2: PQs solicited and managed by NCI Q-Teams [\$20M/yr]

- FY15
  - 12 new PQs for R01/R21 apps (**Spring 2015**)

PQ13 (2011): Can tumors be detected when they are two to three orders of magnitude smaller than those currently detected with in vivo imaging modalities?

research
Harold Varmus & Ed Harlow

Asking and Answering
Provocative Questions



Program Director emily.greenspan@nih.gov



Project Manager michelle.berny-lang@nih.gov

PQB4 (2013): What methods can be devised to characterize the functional state of individual cells within a solid tumor?

## Innovative Molecular Analysis Technology Program in 2015 [\$11M]

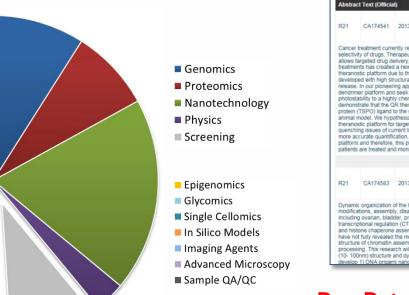




#### http://imat.cancer.gov

Current Year | 2014 | 2013 | 2012 | 2011 | 2010 | 2009 | 2008 | 2007 | 2006 | 2005 | 2004 | 2003 | 2002 | 2001 | 2000 | 1999

Show/Hide All



Award Type	Project#	Year of Award	PI Name(S) All	Institution	Title
Abstrac	t Text (Officia	ıl)			
R21	CA174541	2013	BAI, MINGFENG	UNIVERSITY OF PITTSBURGH AT PITTSBURGH	A NOVEL THERANOSTIC PLATFORM FOR TARGETED CANCER THERAPY AND TREATMENT MONITORING
release. dendrim photosta demons protein ( animal ri theranos quenchi more ac platform	In our pioneer er platform and ability to a high trate that the G TSPO) ligand model. We hyp stic platform for ng issues of cu curate quantifi	ring approach d seek to shift ly chemically at theranosti to the selecte othesize that r targeted car urrent technol cation. It will I , this platform	, we aim to develop the first it. NIR theranostic dendrimers stable, fluorescent and photo conditions and impact the a quaterrylene-based dendrimers and image the a quaterrylene-based dendrincer therapy and efficacy moogy, thus allowing NIR therap possible to conjugate vari	quaterrylene-based (QR) nei away from those with poor o sstable NiR theranostic platfi in targeted cancer imaging, targeted agents in TSPO ov mer will provide a highly pho nitoring. Such innovative des nostic studies with longer im- ous targeting molecules, sign	uition properties, as well as control over drug- ierinfared (NIR) fluorescent theranostic hemical stability, quantum yield and orm. As a proof-clorincipie study to we will attach a conjugable translocator er-excressing breast cancer cells and in an lostable, fluorescent and chemically stable ign avoids the photobleaching and self- ingin avoids the plontobleaching and self- ingin avoids the pland drugs to this innovative t and may transform the way that cancer
potrorno	are irealed an	d morniorea.			
	CA174583	2013	CASTRO, CARLOS E.	OHIO STATE UNIVERSITY	NANOSCALE TOOLS FOR FUNCTIONAL STUDIES OF CANCER-RELEVANT CHROMATIN MODIFICATIONS
R21					

Due Dates: 3/17/15, 6/17/15, and 9/22/15



Tony Dickherber <a href="mailto:eng-dickherber@nih.gov">tony,dickherber@nih.gov</a>

100 active projects (478 to date)

## Acknowledgements/Thanks to the "Secret Ingredients"



#### **Clinical Sciences**























**Life Sciences** 



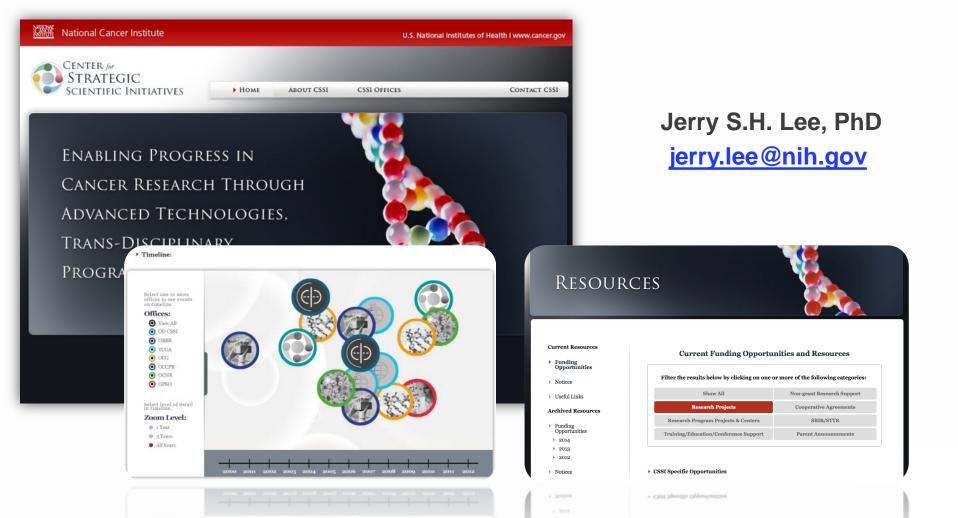




### **Learn More About Us...**



### http://cssi.cancer.gov



## |||||||NIH Early Career Reviewer Program

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- Train and educate qualified scientists
- Help emerging researchers advance their careers by exposing them to review experience
- Enrich the existing pool of NIH reviewers



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J. Thomas Peterson
(Chief of Bioengineering Sciences and Technologies)

http://public.csr.nih.gov/ReviewerResources/BecomeAReviewer/ECR/

#### View the Video!

#### **Inside the NIH Grant Review Process**

CSR has produced a video of a mock study section meeting to provide another inside look at how NIH grant applications are reviewed for scientific and technical merit.

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http://www.csr.nih.gov/Video/Video.asp

